# California Drug Safety Notification

| Notification Name |
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## U. S. FDA Communication: Increased Risk of Mortality and Renal Injury Associated With Hydroxyethyl Starch (HES) Solution Use in Some Patients

| Notification Date | Issue | Recommendation |
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| 06/24/13 | *Hydroxyethyl starch (HES) solutions are used for the treatment of hypovolemia (low blood volume) when plasma volume expansion is desired.*<br><br>*Recent data have associated the use of these products with an increased risk of severe adverse events when used in certain patient populations.* | FDA has concluded that HES solutions should not be used in critically ill adult patients with sepsis and those admitted to the ICU.<br><br>A Boxed Warning to include the risk of mortality and severe renal injury is warranted on the label.<br><br>In addition, FDA has reviewed a meta-analysis of studies conducted in patients undergoing open heart surgery in association with cardiopulmonary bypass and has determined that an additional warning about excessive bleeding is needed in the Warnings and Precautions Section of the package insert. |

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm358271.htm